



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/665,923

09/18/2003

Alphonse Galdes

CIBT-P03-069

1889

28120

7590

06/30/2006

FISH & NEAVE IP GROUP  
ROPES & GRAY LLP  
ONE INTERNATIONAL PLACE  
BOSTON, MA 02110-2624

EXAMINER

BRANNOCK, MICHAEL T

ART UNIT

PAPER NUMBER

1649

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/665,923	<b>Applicant(s)</b> GALDES ET AL.	
	<b>Examiner</b> Michael Brannock	<b>Art Unit</b> 1649	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-16 and 20, as the claims relate to *in vivo* methods, drawn to methods promoting growth, differentiation, or survival of a neuronal cell, classified in class 514, subclass 2.
- II. Claims 1-4, 9-15, as the claims relate to *in vitro* methods, drawn to methods of promoting growth, differentiation, or survival of a neuronal cell, classified in class 514, subclass 2.
- II. Claims 17-19 and 21, drawn hedgehog preparations, classified in class 530, subclass 300.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for “Relationship of Inventions” in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I and II are directed to methods that are distinct both physically and functionally, and are not required one for the other. Group I requires *in vivo* administration and treatments, which is not required by Group II. Group II requires *in vitro* administration, which is not required by Group I. These methods are considered patentably distinct because the two methods require substantially different consideration based upon the location and circumstances of treatment. For example, the modulating *in vivo* activity of a particular product requires consideration of the medical condition which would necessitate such

Art Unit: 1649

treatment, efficacy (e.g. route of administration, dosage amounts, possible interactions with other body compounds and physiological systems) and ability to reach the cellular target. Such considerations are not required for the analysis of methods for product modulating activity in a defined *in vitro* environment, which requires separate considerations with regard to obviousness and enablement including media determination, substrate, and other conditions for growth of target cells and use of the claimed method in culture. The two inventions, therefore, are patentably distinct and although a search of one may overlap that of the other, the search of one could not be relied upon, solely, to provide art that is anticipatory or would render obvious the invention of the other, and to search both inventions would be burdensome.

The hedgehog preparations of Group III are related to the methods of Groups I and II as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the hedgehog preparations of Group III are patentably distinct from each of the methods of Groups I and II because the hedgehog preparations can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups I and II are materially and functionally distinct from each other. Furthermore, the hedgehog preparations of Group I can be used in ways unrelated to the methods of groups I and II such as in the production of antibodies for diagnostic purposes.

Therefore, because these inventions are distinct for the reasons given above and because a search and examination of all the groups in one patent application would result in an undue

Art Unit: 1649

burden, since the searches for the groups are not co-extensive, the classification is different, and the subject matter is divergent, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Claims 1-5, 8-17, and 21 are generic to a plurality of disclosed patentably distinct species of methods of treating disorders, each species consisting of a single identifiable patient population, e.g. Parkinson's disease, domoic acid poisoning, spinal cord trauma etc. Each disorder having divergent symptoms, etiologies, and treatment regimes. Thus, each species involves a patentably distinct method or composition, requiring differing materials, accomplishing divergent goals, the use of one not being required for the use of any other. Furthermore, a search of one could not be relied upon, solely, to provide art that is anticipatory or that might render obvious any other, and to search more than one species in a single

Art Unit: 1649

application would be unduly burdensome. Thus if Applicant elects the invention of Group I or III, then Applicant is further required to elect for prosecution on the merits a single disorder consisting of an identifiable patient population.

Claims 1-20 are generic to a plurality of disclosed patentably distinct species of lipophilic modifications of hedgehog proteins, e.g. myristoyl, palmitoyl, benzene, naphthalene, etc. Each lipophilic molecule being structurally distinct, the use of one not being required for the use of any other. Furthermore, a search of one could not be relied upon, solely, to provide art that is anticipatory or that might render obvious any other, and to search more than one species in a single application would be unduly burdensome. Applicant is further required to elect for prosecution on the merits a single lipophilic molecule.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the

Art Unit: 1649

inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1649

***Conclusion***

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649. Please note the new central fax number for official correspondence below:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867. Official papers filed by fax should be directed to **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB



June 22, 2006



**JANET L. ANDRES**  
**SUPERVISORY PATENT EXAMINER**